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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,521	09/23/2003	Stefan Wintersperger	22649	1880

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,521

Applicant(s)

WINTERSPERGER ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/980,029.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 1/17/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6682742 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al (cited by applicants. The isolated HindIII B fragment and the isolated XhoI E fragment of MVA are taught by Meyer et al. See Figure 2 and also Figures 1 and 5. The presence of an EcoRI site at the position corresponding to position 1063, the ability to hybridize under stringent conditions to SEQ 1, and the ability to integrate into the ATI region are all inherent characteristics of the MVA DNA segment. The reference does not teach applicant's intended use for inserting a heterologous sequence at a restriction site; however, the intended use is not a limitation upon the claimed product. Therefore the reference meets each and every limitation of these claims. Applicant may wish to distinguish the claimed subject matter from plain old MVA ATI-region DNA fragments (which inherently contain numerous restriction sites that could be used for inserting something, and inherently are capable of recombination) by requiring a physical distinguishing characteristic: a multiple cloning site inserted in the MVA ATI-region DNA. Use of a multiple cloning site is described on applicant's specification page 15, lines 23-24.

Claim Rejections - 35 USC § 103

Claims 19-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shida et al (EP 261925) or Paoletti et al (US 5,364,773 or WO 96/39491) in view of Altenburger et al (US 5185146) and Antoine et al (Virology 244:365-396, 1998), for essentially the same reasons as the previous rejection of claims 12 and 14. Applicant argues that the ATI region of MVA differs extremely and substantially from the ATI region of all other poxviruses, especially vaccinia virus. Applicant argues that, because vaccinia virus has deleted parts of the nonessential ATI gene and MVA has deleted even more of the ATI gene, this region is unstable and unsuitable for insertion of heterologous genes. "Since the ATI region of MVA has proven unsuitable even for viral genes, one skilled in the art would have expected that when inserting foreign genes into that region, these genes would of course be deleted, during further replication cycles." The same argument could be made with equal force against the ATI region in vaccinia, and is countered by the success of those in the art in using the ATI region of vaccinia for insertion of heterologous material. Applicant argues that Meyer teaches instability of the terminal regions during continuous propagation in cell cultures. This is equally applicable to other strains of vaccinia, which has not discouraged those in the art. In addition, the standard for obviousness is not absolute predictability, but a reasonable expectation of success. In spite of some differences between the ATI region of MVA and the ATI region of other vaccinia after 574 passages in culture, in spite of some uncertainty regarding the stability of an insertion on further extended passage, it is

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maintained that the successful use of the ATI region in other vaccinia strains is sufficient to suggest the ATI region in MVA, with reasonable expectation of success.

Claims 19-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter et al WO 97/02355 in view of Meyer et al (cited by applicants) and Antoine et al (Virology 244:365-396, 1998). Sutter teaches that six major deletions of genomic DNA have been identified, and refers to Meyer. Sutter explicitly suggests recombining a foreign DNA precisely at the site of a naturally occurring deletion. See for example page 4 and claims 1, 3-28. Sutter provides a working example using deletion II, and does not mention any problems with instability, viral propagation, or replication efficiency. Meyer teaches the location of the other naturally occurring deletions, and Antoine teaches the sequence surrounding the deletions. Since the ATI region contains deletion IV, insertion of foreign DNA at deletion IV is seen as obvious. It is noted that Sutter does not teach insertion of foreign DNA at the EcoRI site in the ATI region. However, none of applicant's claims actually require insertion of foreign DNA at the EcoRI site; they only require the EcoRI site to be present in the DNA. Again, the intended use of the EcoRI site does not limit the subject matter of the claims.

Double Patenting

Claims 19-52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-33 of U.S. Patent No. 6,440,422 in view of Meyer et al (cited by applicants) and Antoine et al (Virology 244:365-396, 1998). The patent claims recombinant MVA with a foreign gene inserted in a naturally occurring deletion, including site IV. As discussed above, Meyer discusses

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the location of site IV, and Antoine teaches the sequence of the flanking region.

Therefore, the instant claimed subject matter encompasses obvious embodiments of the previously claimed viruses, and DNA intermediates required to construct the obvious embodiments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/30/06


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER